New Cleaning Processes: Oxivario and Other Multi-Component Procedures

Validation following ISO TS 15883-5

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B.2.6.2 Surgical instruments

One instrument tray with:

• 20 Mayo scissors, curved, 14 cm, stainless steel, polished clean, not lubricated;
• 20 forceps, Crile, curved, 14 cm, stainless steel, polished clean, not lubricated.

B.2.8.2 Surgical instruments

Load the WD with the test instruments on their tray. If the WD can take additional instrument trays, fill it with clean surgical instruments on their trays according to the manufacturers instructions. If the WD can take more than four but less than nine instrument trays simultaneously, two of these should be with test instruments according to B.2.7.2. If it can take more than eight trays simultaneously, three of these should be with test instruments according to B.2.7.2.

B.2.9.2 Acceptance

For the cleaning efficiency of the WD to be deemed acceptable at least 95% of all test objects for each test object type under test should be clean.
Investigations Following the Standard ISO TS 15883-5

BH 145R
(lower sieve basket)

BH 425R
(upper sieve basket)
Contamination of the artery clamps with 100μl coagulable sheep blood

Correlation of the Radionuclide Method with the OPA-Method

The radionuclide method can only be used in the laboratory, but the results of the tests are not influenced by the quality of the recovery procedure. Therefore the experiments in practice have to be performed with the Biuret- or modified OPA-Method.

Radionuclide method

- Standardized in-vitro contamination
- Quantification of residues
- Detection of critical spots
- Method for validation of cleaning behavior
- The results of RNM and OPA-method correlate
Correlation between RNM- and OPA-Method

Cleaning process: Foaming
Cleaning process: Foaming

Dosing of the detergent:
Pressure goes down from 0,2 bar to 0,1 bar
Stable water pressure by higher water level
Influence of the pre-cleaning

Initial contamination of each instrument was 120 counts/sec

Comparison pre-cleaning and main wash

Influence of the pre-cleaning

Oxivario Program (reduced cycle)

- 2 min cold pre-wash using tap water
- Drainage
- 2.5 min wash at 55°C using 0.5% alkaline detergent
- Drainage
- 2.5 min wash at 55°C using 0.5% alkaline detergent and an oxidative additive 0.35%
- 1 min neutralisation at 38°C using an acid additive (0.1 %) based on citric acid
- Drainage
- 1 min intermediate rinse
- Drainage
- 1 min intermediate rinse
Investigated detergents

Alkaline detergent A (phosphate, disodium- and potassium-metasilicate, tenside-free, with and without an oxidative additive B (hydrogen peroxide solution somewhat less than 30%) in the second wash step

Also the oxidative additive was tested in different concentrations (0.175 % and 0.35 %)

Alkaline detergent C (sodium phosphate, sodium silicate, potassium hydroxide, tenside-free) with and without an oxidative additive D (hydrogen peroxide solution somewhat more than 30%) in the second wash step at a concentration of 0.35%

Mildly alkaline detergent E (enzymes, tenside, caustic potash solution) with and without oxidative additive B
## pH-values of the applied concentrations of detergents

<table>
<thead>
<tr>
<th>Detergent and concentration</th>
<th>pH-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alkaline detergent A 0,5%</td>
<td>11,2</td>
</tr>
<tr>
<td>Alkaline detergent A 0,5% &amp; H₂O₂ 0,175% (oxidative additive B)</td>
<td>10,9</td>
</tr>
<tr>
<td>Alkaline detergent A 0,5% &amp; H₂O₂ 0,35% (oxidative additive B)</td>
<td>10,4</td>
</tr>
<tr>
<td>Alkaline detergent B 0,5% &amp; H₂O₂ 0,35% (oxidative additive D)</td>
<td>11,1</td>
</tr>
<tr>
<td>Alkaline detergent E 0,5%</td>
<td>9,8</td>
</tr>
<tr>
<td>Alkaline detergent E 0,5% &amp; H₂O₂ 0,35% (oxidative additive B)</td>
<td>9,2</td>
</tr>
</tbody>
</table>
Reduced cycle investigations:

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Anzahl der Klemmen über dem Grenzwert

Discussion (1)

The test method described in the standard ISO 15883, when combined with the RNM, proves to be a suitable way of comparing the different wash processes with one another.

The question is then whether the principle of using a partial or half cycle of wash steps to gain improved differentiation, should be used for WDs - as it has already been used to validate sterilisation.

At the moment wash tests are carried out without any safety net, which means that no performance reserves are taken into account to deal with fluctuations that may occur in the practical situation, for example by drying-on of soil.
Because the clamps were contaminated in a defined way with a pipette, a standardised starting contamination could be assured. Thus it can be shown that the results of washing with the Oxivario programme without an oxidative effect are definitely inferior, and also that the statistical deviation increases.

Even at a low hydrogen peroxide concentration there was more constant washing with fewer differences in washing results. Another result of the Oxivario process with added hydrogen peroxide is the proven cleaning effectiveness, even in areas that are difficult to reach. This special deep cleaning makes the process superior in comparison to the alkaline process run without an oxidative additive.
Colourchange with colour coded Titanium screws after cycles with Oxivario
Exposition of blue anodised Aluminium plates

for 1 hour bei 55°C

Alcaline detergent solution adjusted to
pH 8,0 – 9,0 – 10,0 – 11,0
Exposition of blue anodised Aluminium plates for 1 hour bei 55°C

Hydrogen peroxide (0.35 %) solution with an alkaline detergent adjusted to pH 8,0 – 9,0 – 10,0 – 11,0
Orthovario Process

- DOS at 50 °C tenside cleaner, 0.4 and alc. cleaner, 0.2
- DOS at 40 °C tenside cleaner 0.4
- DOS Neutr.
- Desinfection
- Drying

DOS in %

pH 10.0 - 10.5
Colored anodised Aluminium
new untreated plate

Plate after 65 cycles with the processes
Vario at pH 10.0 - Orthovario at pH 10.2
Conclusion

The radionuclide method was used to investigate comparatively the cleaning performance of automatic washing/disinfection processes on the critical joint areas of artery clips. The defined initial soil was radioactively marked coagulable blood.

Washing using the Miele Oxivario process with the addition of hydrogen peroxide achieves an increased cleaning performance compared to that from the alkaline detergent alone, and also attains better results in critical areas, so that the cleaning performance is standardised at high level.

With the Orthovario process the same good cleaning results can be obtained, without having the corrosive changes of the anodized surfaces.
Thank you for your attention

Further informations

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